Unit Three
Knowing Where & How to Look for Meaningful Evidence

Core Skill #1 Asking Answerable Questions

Difficulty asking a precise and focused clinical question can be a major impediment to EBP. Clarifying the question is fundamental in getting you to the best potential sources of evidence. Try this mnemonic: PICO [pronounced pie-co or p-co]==> it will help you to formulate a question.

P = patients or populations
I = Interventions or interests
C = Comparison group or the gold standard [Melnyk/Fineout 2004]
O = Outcome desired

1. **Using our clinical example:**

P = Will family members of patients
I = who are present during resuscitation
C = compared to family not present
O = have an increase of benefits or harms?

Now then let's consider some other practice issues:

2. **Women who have elevated diastolic pressures:**

P = Do women ≥ 60 yo
I = whose diastolic pressure ≥ 95
C = compared to women with normal diastolic pressure
O = have an associated increase risk of stroke?

3. **Continuation of meds perioperatively:**

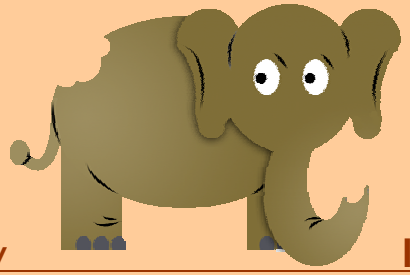
P = For patients undergoing general anesthesia
I = is continuation of 'statins' perioperatively
C = compared to no 'statins' perioperatively
O = associated with increased risk of rhabdomyolysis?

4. **Showering post surgery:**

P = In patients who have moderate incisions
I = does showering within the first 48 hours post op
C = compared to keeping incision dry and covered for least 48-72 hours
O = convey an increase risk of infection or wound dehiscence?

Medical databases also like to use question domains:

- Therapy—is this **XYZ** therapy better than the standard of care?
- Diagnosis—does this set of symptoms represent this condition?
- Prognoses—if we do **RZQ,** will the patient preserve quality of life, more than if we do not do **RZQ**?
- Harm or Causality--does smoking cause cancer?

Core Skill #2 Searching effectively  let's do this one bite at a time!

Strong Recommendation: take the University of Virginia course on "Information Mastery" it takes time but at the end you will feel **so confident** about searching effectively: http://www.healthsystem.virginia.edu/internet/library/collections/ebm/index.cfm

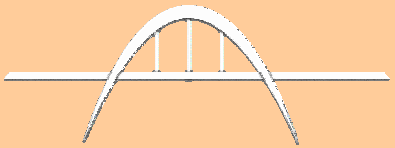
Here is a great set of EBP tools from the University of Washington: http://healthlinks.washington.edu/ebp/ebptools.html

Evidence searching depends on a number of factors

- Available time - **limited but obtainable**
- Available data bases and computers - **we are fortunate with multiple databases**
- PICO question formulation and identifying the domain of the topic - **skill #1(asking an answerable question) comes with practice, practice, practice**

On the Standard Clinical Desktop [SCD] are 3 databases: Cochrane, Pub Med, and Cinahl.

Judy Welsh has 2 excellent tutorials on how to access articles from each of these data bases and EBP in general. Go to,
http:// nihlibrary.ors.nih.gov/JW/informationist.html



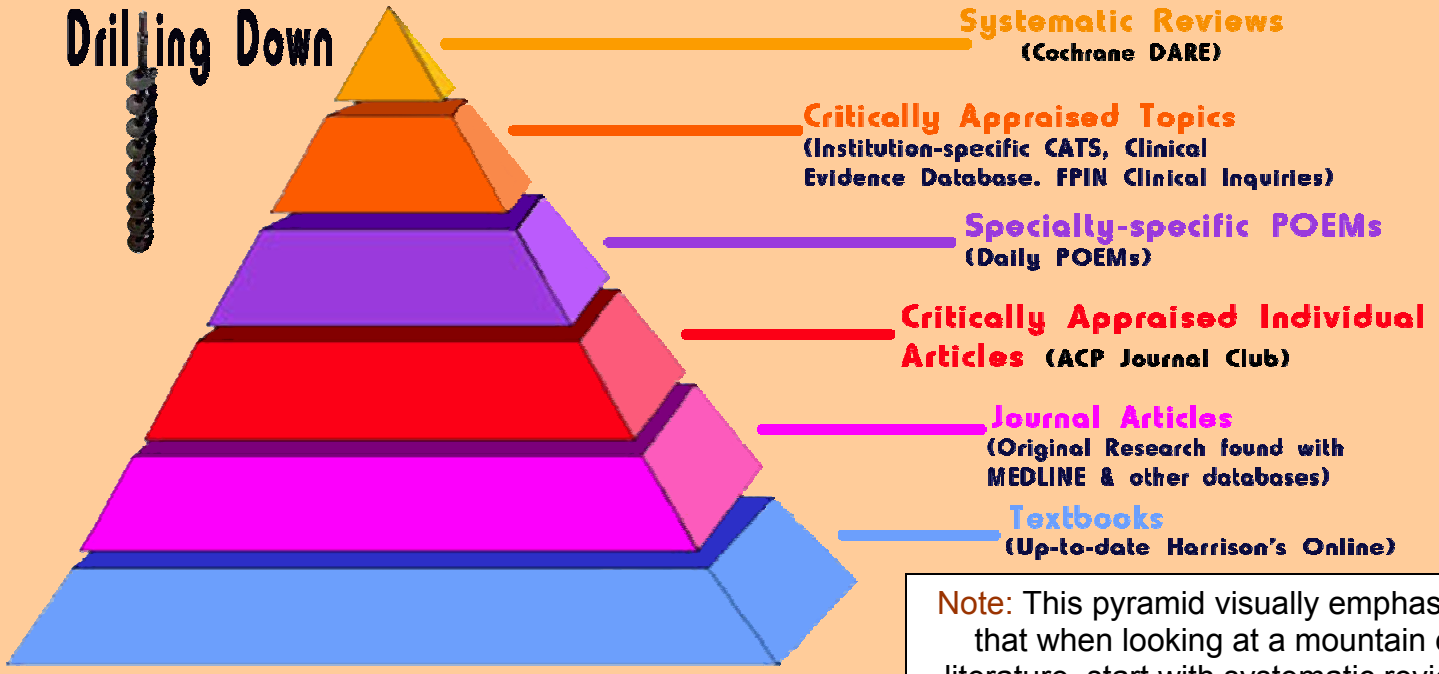
Other Databases to consider for ***ADVANCED*** searching skills:

Resource	Provides evidence rating	Focus on Pt. Outcome	Easy to Use	Recommends clinical action	Available @ Point of Care	Regularly Updated @ least monthly
Cinahl Care Sheets	✓	✓	✓	✓	✓	✓
TRIP	✓	✓		✓		
Cochrane	✓	✓	✓	✓	✓	✓
AHRQ	✓	✓		✓		✓
Bandolier	✓	✓	✓	✓		✓
DARE	✓	✓		✓	✓	✓
Up to Date	✓	✓	✓	✓	✓	✓
National Guidelines	✓	✓		✓	✓	

InfoPOEMs
The Clinical Awareness System™

This data base is not available in the library. However some of the neighboring Universities have this accessible. It is the only database of filtered synopsized EBP information, reviews, poems, decision support tools, summaries of EBP practice guidelines and 5minute clinical consults. It is a very user friendly site that is quite good. You can take the tour for free and there is available a free 30 day trial.

No putting on a happy face... Scaling the mountain of literature efficiently and effectively does take time and skill, but UVA uses "the secrets of the pyramids" as a tool to help you:

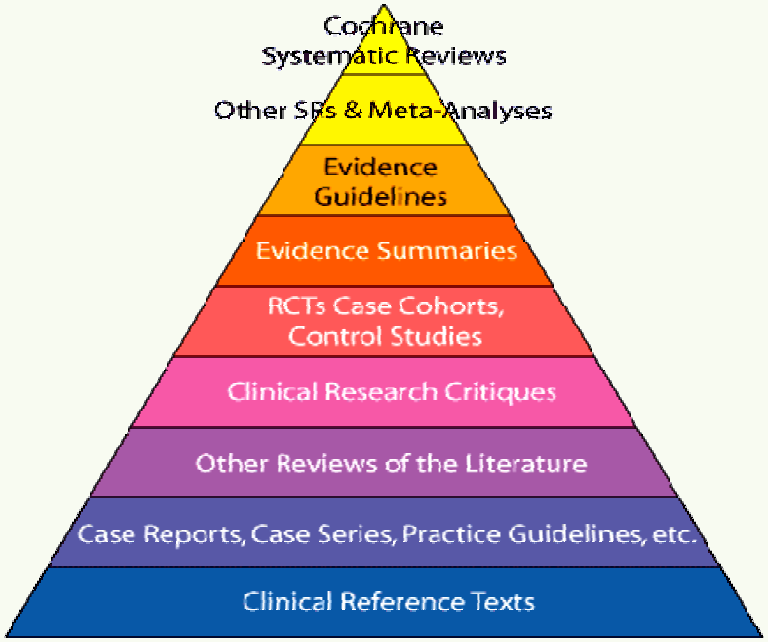


Modification of UVa Information Mastery Pyramid

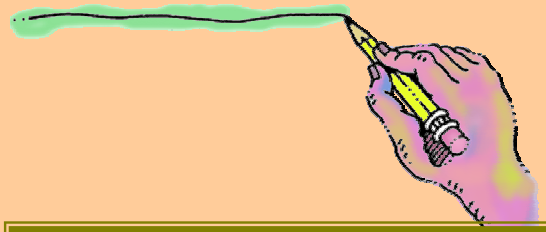
Note: This pyramid visually emphasizes that when looking at a mountain of literature, start with systematic reviews and then drill down to others. The others may take more time to access and may have less study quality/strength.

From the NIH librarian's EBP Tutorial http://nihlibrary.ors.nih.gov/JW/informationist.html
This is another pyramid, [U of Washingto EBP Tools], that emphasizes starting with systematic reviews.

Searching for the Best Evidence



Bottom Line ….. Do I have to go through all that trouble?

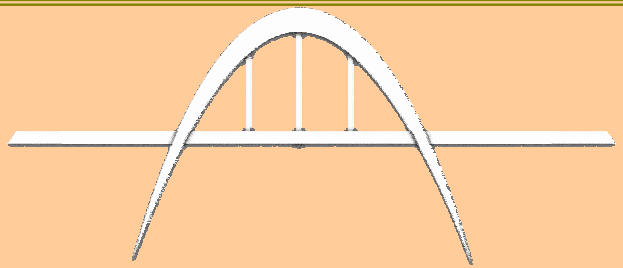


No You Do Not!

You are a busy clinician with limited time and who is also committed to having an *up to date* practice. Let the experts do the complicated, time-consuming task of searching the literature, filtering it for relevance, and using levels of strength and validity.

1. Use systematic review databases such as Cochrane
2. Use Health Professional Association Databases such as ONS
3. Click on the SCD databases; don't forget to use the limits box

Remember: the librarian is available to help with any question re: journal searching and EBP when you get stuck. Send an email request to welshju@mail.nih.gov See her tutorials: http://nihlibrary.ors.nih.gov/JW/informationist.html



Core Skill #3 Appraising Articles Critically

For the **BEGINNING** EBP practitioner just 3 considerations are necessary:

Is the evidence ***valid***, ***reliable*** and ***applicable?***

"***Applicable"*** ***(from AAFP 2004-06)*** **[Consider some of these questions when reading the abstract]**

- Is this a problem I see on my unit?
- Does the patient population in this study look like my patient population?
- Is the intervention realistic on my unit?
- What is the intervention being compared to—is it a reasonable comparison?
- Would the outcomes matter to my patients?
- Is the number of patients appropriate to the study design?
- Does the study tell me how many patients one needs to treat before one patient will benefit?
- Is the evidence comprehensive; does it answer the majority of my clinical practice questions on the topic?
- Is the information filtered to focus on the most relevant information that actually addresses patient outcomes?
- Does it offer a final recommendation?
- Can the results be immediately applied to my patients?
- What are the chances that a patient might experience an adverse event with the intervention?

"Valid"

- Does the study actually measure what it intends to measure?
- Did every participant have an equal chance at being chosen?
- Is the control group similar to the experimental group?

Validity Questions are Cumulative...

Can we generalize to other persons, places, and times?

Can we generalize to the constructs? abstract, image, idea, or theory, especially a complex one, formed from a number of simpler observable elements.

Is the relationship causal?

Is there a relationship between the cause and effect?

William M.K. Trochim

"Reliable"

- How precise are the measurements?
- Are the results reproducible?
- Does multiple testing produce consistent results?
- Are the results reproducible in any clinical environment, any clinical population?

More Advanced Skills from our RAPDS EBP Mentor: Sandra Mitchell

Critically Appraising Clinical Guidelines

- Why was the guideline developed?
- What is the composition (expertise and disciplinary perspective) of the panel that developed the guideline?
- What entity provided financial sponsorship?
- What decision making process was used in developing the guideline?
- What clinical question was the guideline developed to address?
- How was the evidence used in the guideline gathered and evaluated?
- Were gaps in the evidence explicitly identified?
- How explicitly is the evidence linked to the recommendations in the guideline?
- If lower levels of evidence are incorporated how explicitly is this labeled? Are the reasons for the inclusion of expert opinion, the line of reasoning and the strength of extrapolation from other data clearly identified?
- How are patient values/preferences incorporated into the guideline?
- Is cost effectiveness considered?
- What is the mechanism and interval for updating the guideline?

Critically Appraising the Literature

- The goal is to evaluate the scientific merit and potential clinical applicability of each study's findings or a group of studies covering similar problem areas to determine what findings have a strong enough basis to be used in clinical practice.
- Scientific merit-design, measurement, sample, data collection procedures, data analyses
- Balanced & respectful. If contradictory evidence exists, consider the full scope of the controversy.
- Critical appraisal is like any other skill. We learn it through practice - practice - practice **AND** dialogue with others (e.g. journal clubs)
- Journal club and colleague discussions are ideal ways to develop skills in critical appraisal.
- Are the number & type of patients unique or typical?
- Is there any doubt that the intervention (independent variable) led to the outcomes?
- Are the conclusions of the study based upon statistically significant findings?
- Are the results comparable to other similar studies?

Core Skill #4 Minimum Health Numeracy the beginning steps

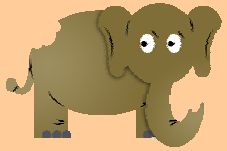
Take this quiz that is routinely given to DUKE UNIVERSITY Medical students:

1. If you flip a coin 1000 times how many times would you expect to come up with heads?
2. There is a 1% chance of winning the lottery. If a 1000 people bought one ticket each, how many would win?
3. In the NIH sweepstakes the chances of winning a microscope are 1 in 100. What % of tickets wins the microscope?

Answers are at the end of Unit IV

Health numeracy [fancy new, but neat term] is defined as the degree to which individuals have the capacity to access, process, interpret, communicate and act on numerical quantitative, graphical, biostatistical, and probabilistic health information needed to make effective healthcare decisions (Bandolier, 2006).

Are you a little intimidated?—Again one bite at a time



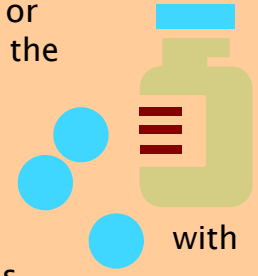
Let's go over some terms that the literature often uses (Cockburn, 2006).

P values = this does not always mean *phenomenal*  *;* the p stands for probability. P value tells the investigator the probability that the observed results are due to chance alone. The values range from 0.0 to 1.0; the smaller the value the lower the probability the results occurred by chance. The P value, p= 0.001, is interpreted as 1 in 1000 chance that the result is by chance. The probability of 0.05 is the level generally accepted as study significance. Again, the p value helps you to determine if the observed effect/relationship/differences happened by pure chance. It is a reliable indicator of the relationship between variables.

P- Value example = You have a meal Buddy who always wants restaurant choices decided by flipping his quarter, you suspect that the quarter is rigged. Buddy always calls 'heads' and he usually wins. You ask to do an experiment with his coin in order to decide if the coin is different than an ordinary quarter—the null hypothesis would be the coin is like any other quarter. An alternative hypothesis is that the coin is different. Evidence says that if you flip an ordinary two sided coin, one would expect that approximately 50% of the time one would get heads. You flip Bud's coin 25 times and 20 times you get heads and 5 times you get tails. You toss it for another 25 times and get the same results. In others words, heads comes up 80% of the time instead of the expected 50%. You take the experiment's results to a statistician and pose the question: How likely is it that this coin produced head 40 times out of 50 tosses? She reports that based on your observations, this coin is different than an ordinary quarter and the p value is 0.00176 (in other words the likelihood of this conclusion being wrong is less than 2 chances in 1000!). Next time you will not flip with Bud's coin.

Confidence Intervals = is a value reported in % & sometimes followed by a range of upper and lower limits of the results, i.e. 95% CI 28-40. This means that if the study were repeated 100 times then 95 times the result would be true and the values would fall between 28 and 40; putting it another way there is a 1 in 20 chance that the results *will* fall outside the range. Example = you are a quality officer assuring that 50ml IV mini-bags are truly 50 mls. You take a sample of 32 bags off the pharmacy shelf. You use a calibrated instrument to measure the fluid in each bag and get 32 different amounts. Adding them altogether the average amount is 50. 3 ml. You repeat your measures on another 32 bags and the average of all the measures is 50.2 ml. A statistician looks at your results and reports that the confidence interval at 95% CI 49.7- 50.4. This means 95% of the time; one can expect that the 50ml bags will contain fluid between 49.7 and 50.4 ml.

Power = the number of subjects that must be enrolled in the study in order to detect an effect or significant results. Power is "the ability of a given statistical test to detect an effect, certain that the effect actually exists" [R. High University of Oregon] It is based on 4 elements: number of patients available, the strength of the treatment effect, the odds that the observed result is due to chance, and the odds that you will observe a treatment effect when the treatment occurs. Example: Suppose you want to prove that the number of pills [meds] affects adherence. In designing the study you would have to consider how many subjects it would take to conclude with 95% certainty (p = .05) that as the number of pills increases, the compliance with taking them is adversely affected.



OPTIONAL but Definitely Advanced Statistical Concepts

ODDS = the odds of an event taking place in a group is the number of times it occurs in that group divided by the number of times that it does not occur. >1 = event occurred more often in the treatment group. 1 = event occurred equally in the two groups <1 = event occurred more often in the control group.

ODDS RATIO= the odds that a specified event occurring in the treatment group divided by the odds of it occurring in the control group. It is most often expressed as %. >1 = event occurred more often in treatment group; 1 = event occurred equally in treatment and control; 0-1 = event occurred more often in the control group.

Risk = Rate of occurrence of the specified event in a treatment or control group. Risk can be described as adverse or beneficial; it is the number of events that occurred in a group divided by the total number in the group. 1 = Event occurred in the entire treatment or control group 0= absence of the event.

Relative Risk or Risk Ratio = this compares the risk of the event occurring in the treatment group relative to the risk in the control group. RR of over 0.5 is considered to clinically relevant; RR of .25 to .5 is probably clinically relevant. >1 more events occurred in treated group 1 = events were equal in the groups 0 to 1 = more events occurred in the control group.

Relative Risk Reduction = this is a measure of the proportion of subjects who avoided a bad outcome because of the treatment when compared with controls who had a different treatment, placebo or no treatment. 0 = no effect in the treatment group beyond that of the control 0.5 = risk of effect occurring is halved in treatment group 1= risk reduced to zero.

Absolute Risk Reduction = useful when treatment provides protection against an adverse outcome. ARR = 1.0 events occurred only in the treated group and none in the controls; ARR of 0 = event rate is the same in treated and control groups so there is no change in risk as a result of treatment.

Number needed to treat = the number of subjects who would need to be treated to obtain the specified outcome in one subject [1 divided by the risk in the treatment group minus the risk in the control group]. 1 = more beneficial events occurred in the treatment group than the control; 2-4 is considered a good outcome. NNT of 1 means all subjects in treated group had the beneficial event and no beneficial event occurred in the control group. NNT of <1 = more events occurred in the control than the treated group.

EXAMPLE: of Applying the Optional Advanced Statistical Concepts

	Beneficial Results	No Beneficial Results	Total Sample Number
Wonder Drug Treatment	140 (A)	80(B)	220
Standard Treatment Control	120 (C)	100 (D)	220

Calculate the odds ratio: A/B ÷ C/D 140/80 = 1.75; 120/100 = 1.2; 1.75/1.2 = 1.46 This can be interpreted as the beneficial event occurred more in the treatment group than in the control group. *Good right?*

Now calculate the risk ratio :1- A/A+B divided by C/ C+D ; 140/220 ÷ 120/220 ; 0.636 ÷0.545 =1.166; 1-1.166= 0.166 This can be interpreted as *not as exciting*; Only ~ 17% of time does the treatment get the beneficial effect beyond the control group.

Now calculate the NNT [the number needed to treat: how long would it take to get to the first patient who receives the beneficial result?
1÷ (a/a+b- c/c+d) : 0.636-0.545= .091; 1/.091= 11 *Wow… looking even worse!*

BUT>>>What if the wonder drug had some adverse reactions or like most new drugs was very expensive? Would it be worth considering?? Maybe not. Now then, suppose the wonder drug was for a serious life-threatening condition. One might want even a small chance of benefit making the cost of the treatment worth the chance of extended life. **Life axiom; there are no 'PAT' answers.**

HAD ENOUGH STATISTICS?

From the JAMA Article Sept 6, 2006 Vol 296, No. 9
A Systematic Review by T. Shaneyfelt, et. al.

EBP Domains

Ask: Converting the need for information about prevention, diagnosis, prognosis, therapy, causation into an answerable question

Acquire: Tracking down the best evidence with which to answer that question

Appraise: Critically appraising that evidence for its validity (closeness to the truth) impact (size of effect) and applicability (usefulness in one's own practice).

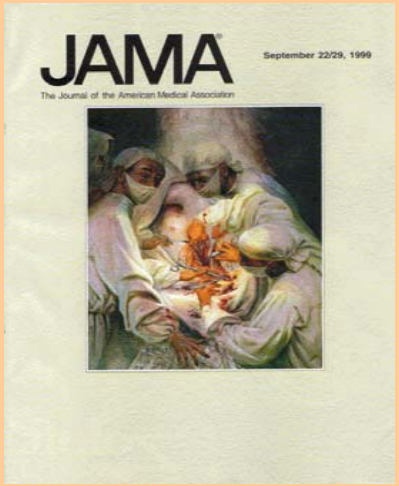
Apply: Applying the evidence in clinical decision making and integrating the evidence with the patient's preferences and particular clinical circumstances.

EBP Behaviors

Enacting EBP steps in practice: actually enacting the EBP steps in the course of patient care activities.

Performing EB clinical maneuvers: performing EBP in actual practice- applying the evidence from the literature to appropriate patient situations.

Affecting patient outcomes: the practitioner's patients experience improved or favorable outcomes, such as, lower blood pressure.



? ? ? ? ? ? ? ?

What do we do if there is insufficient, conflicting or weak evidence??

CREATE BETTER EVIDENCE!

Other options:

1. Let the provider team decide on the intervention
2. Present the patient with all the available information and let the patient decide
3. If low risk - try an intervention and see if it works for the patient
4. Deliver the intervention that is the professional community standard

Are you thinking,  " yeah right! , how am I going to get all this into my daily practice?"—then proceed to Unit IV for some hints.